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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,153	09/13/2000	Matthew A. Howard III	UIOWA-8PAD1	7887

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EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/661,153	HOWARD III, MATTHEW A.	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-10,12-15,41-44,52,53,56,57,59-64 and 66-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *63,64,67-70,85 and 88* is/are allowed.

6)☒ Claim(s) *8-10,12,41,43,52,53,57,59,60,62,71,73,74,77,79,83,86,89,92 and 94* is/are rejected.

7)☒ Claim(s) *13-15,42,44,56,61,66,72,75,76,78,80-82,84,87,90,91 and 93* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 September 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The indicated allowable subject matter of claims 9-10,43,57,59-60,74,77 and 79 is withdrawn in view of the newly discovered reference(s). Rejections based on the newly cited reference(s) follow.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claims 44 and 84 recite "a controller" which controls the drug delivery ports. This controller is not recited in the specification.

Claim Objections

Claims 8,12-14,41,80 and 82-83 are objected to because of the following informalities: all claims recite "a drug reservoir/pump". While the examiner assumes, based on the specification, that this limitation is referring to a reservoir pump the backslash "/" renders the recitation confusing. One could assume that the limitation is referring to a reservoir or pump. It is suggested that applicant rewrite the limitation as –a drug reservoir pump--.

Claim 66 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 66 contains the same

subject matter but recites "microcatheter" instead of "microinfusion catheter" as is stated in claim 63.

Claim 66 is objected to because of the following informalities: The claim recites "microcatheter" and the independent claim recites "microinfusion catheter". While it is understood that the term "microcatheter" is referring to the "microinfusion catheter" it is suggested that consistent terminology be used throughout the claims to avoid confusion. Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

1. the embodiment of claim 82 that includes a plurality of microinfusion catheters where at least one microinfusion catheter is configured with a plurality of individually controllable ports where each of the catheters is functionally coupled to a manifold which is functionally coupled to a drug supply line where a pump is functionally coupled to the drug supply line.
2. the "controller" of claims 44 and 84.

These features of the claims must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53, 60 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (US pat# 5,531,679). Schulman discloses a fluidic infusion system for a catheter that includes a plurality of non-coaxial infusion catheters (12'), a macrocatheter (10) for housing the infusion catheters, a pump (P1) and a manifold (26'). See figure 6. The device further includes at least one electrode (27) which is configured (in that electrodes are metal) to sense electrical activity of the brain. See 9:42.

Schulman meets the claim limitations as described above but fails to teach the plurality of non-coaxial infusion catheters being microinfusion catheters. However, at the time of the invention, it would have been obvious to make the device of Schulman on a small scale. Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Additionally, the motivation to make the device of Schulman a very small device in size or caliber would have been in order to accommodate much smaller vessels such as arterioles.

Regarding claim 62, Schulman meets the claim limitations as described above but fails to include that the drug is an appetite controlling drug. However, at the time of the invention, it would have been obvious to incorporate any drug, including an appetite controlling drug, into the invention of Schulman. Any drug would meet the purpose of the invention of Schulman, i.e. a device designed to introduce a drug into a target site within the body. Hence, it would be obvious to incorporate any drug, including an appetite suppressing drug, into the invention of Schulman since the invention is designed for that purpose.

Claims 8,12,41,52-53,57,71,73,77,79,92 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al (US pat# 5,772,629). Kaplan discloses a plurality of non-coaxial infusion catheters (126), a macrocatheter (GC) for housing the infusion catheters, a pump (see 7:45) and a manifold (114). See figures 1-2 and 11. The

device further includes a drug supply line (116) and infusion ports along the length of the catheters (128). A syringe (see 7:45) is capable of pumping at a variable rate.

Kaplan meets the claim limitations as described above but fails to teach the plurality of non-coaxial infusion catheters being microinfusion catheters. However, at the time of the invention, it would have been obvious to make the device of Kaplan on a small scale. Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Additionally, the motivation to make the device of Kaplan a very small device in size or caliber would have been in order to accommodate much smaller vessels such as arterioles.

Regarding claim 41, Kaplan meets the claim limitations as described above but fails to include that the drug is an appetite controlling drug. However, at the time of the invention, it would have been obvious to incorporate any drug, including an appetite controlling drug, into the invention of Kaplan. Any drug would meet the purpose of the invention of Kaplan, i.e. a device designed to introduce a drug into a target site within the body. Hence, it would be obvious to incorporate any drug, including an appetite suppressing drug, into the invention of Kaplan since the invention is designed for that purpose.

Claims 9-10,43,59,74,83 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan in view of Scheinman et al (US Pat# 5,429,131). Kaplan meets

the claim limitations as described above but fails to include the macrocatheter having a magnet or the device having monitoring electrodes.

However, Scheinman discloses the teaching of using sensing electrodes and magnetized electrodes for sensing the electrical impulses in the heart and for tracking the positioning of the catheter within the heart. The sensing electrodes provide a map of the heart.

At the time of the invention, it would have been obvious to incorporate the electrodes for both mapping and tracking into the invention of Kaplan. Both devices are analogous in the art and therefore a combination is proper. Additionally, both devices are designed for cardiac use and treatment. Furthermore, the motivation for incorporating would have been in order to provide the device of Kaplan with an enhanced method of device positioning within the body to easily and accurately carry out the procedure thereby enhancing the overall safety of the patient.

Allowable Subject Matter

Claims 63,64,67-70,85 and 88 are allowed.

Claims 13-15,42,44,56,61,66,72,75,76,78,80-82,84,87,90,91 and 93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: the allowability of the independent claims above is based on the combination of all the limitations within each claim.

Regarding claims 63 and 88, the prior art fails to teach a drug infusion device having the combination of a plurality of non-coaxial microinfusion catheters where at least one microinfusion catheter comprises a plurality of individually controllable drug delivery ports disposed along a length of the at least one microinfusion catheter and a macrocatheter configured to house the plurality of microinfusion catheters.

Regarding claim 85, the prior art fails to teach a drug infusion device having the combination of a plurality of non-coaxial microinfusion catheters where at least one microinfusion catheter comprises a plurality of individually controllable drug delivery ports disposed along a length of the at least one microinfusion catheter, a pump configured to controllably supply a drug to the plurality of microinfusion catheters and a manifold configured to convey the drug from the pump to the plurality of microinfusion catheters.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams CSW.
June 17, 2004

LOAN H. THANH
PRIMARY EXAMINER